# IMPLANTABLE DEVICE USING ULTRA-NANOCRYSTALLINE DIAMOND

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## Cross Reference to Related Applications

[0001] This application claims the benefit of U.S. Provisional application No. 60/272,962, filed February 28, 2001. This application is related to U.S. Patent application, Implantable Microfluidic Delivery System Using Ultra-Nanocrystalline Diamond Coating, Attn. Docket No. S111-USA, filed on even date herewith and incorporated herein by reference.

## Field of the Invention

[0002] The present invention relates to an implantable device that communicates with living tissue, wherein electronic circuitry associated with the implantable device is coated with a thin film that is biocompatible and hermetic.

## Background of the Invention

[0003] Hermetic electrically insulating materials are desirable for packaging of electronics in implantable stimulating and sensing devices, where implantation is in living tissue in a living body. The implanted devices must be biocompatible. The devices must not only exhibit the ability to resist the aggressive environment present in the body, but must also be compatible with both the living tissue and with the other materials of construction for the device itself. The materials are selected to avoid both galvanic and electrolytic corrosion. Typical materials of construction for implantable devices include ceramics, plastics, or metals. The ceramics may be glass, or a metal oxide, such as alumina, titania, zirconia, stabilized-zirconia, partially-stabilized zirconia, tetragonal zirconia, magnesia-stabilized zirconia, ceria-stabilized zirconia, yttria-stabilized zirconia, or calcia-stabilized zirconia, or yttria-stabilized zirconia, although other ceramic materials may also be used. The plastics may be epoxy, polycarbonate, or plexiglass. Typical metals include titanium or titanium alloy (such as Ti- 6 Al- 4 V), although other metals, such as platinum, iridium, platinum-iridium, stainless steel, tantalum, niobium, or zirconium may be used.

[0004] One solution to achieving biocompatibility, hermeticity, and galvanic and electrolytic compatibility for an implanted device is to encase the device in a protective environment. It is well known to encase implantable devices with glass or with a case of ceramic or metal. Schulman, et al. (U.S. Pat. No. 5,750,926) is one example of this technique. It is also known to use alumina as a case material for an implanted device as disclosed in U.S. Pat. No. 4,991,582. These cases are often too thick for use with miniature implantable devices, such as the prosthetic retinal implants of Second Sight, LLP. The case unacceptably increases the size of the device and becomes a limiting factor as to where the devices may be placed in the body.

[0005] It is also known to protect an implantable device with a thin layer or layers of an electrically insulating, protective material, as disclosed by Schulman, et al. (U.S. Pat. No. 6,043,437). Coatings of alumina, zirconia, or other ceramic, less than 25 microns thick, were applied by evaporative coating, vapor deposition, or ion-beam deposition.

[0006] Disadvantageously, the sensor described in the referenced patent and patent applications is relatively thick. For some applications, where small size is required, such as when a device is placed in an eye, eyelid, or in a fingertip, space is very limited and only a very small device will fit. There remains a need for yet a smaller sensor or a stimulator that performs all of the same functions as the prior apparatus, i.e., that provides working electrodes exposed to living tissue, perhaps with a selected enzyme placed over one electrode, and with hermetically-sealed electronic circuitry controlling the stimulator or sensor and communicating with other internal or external devices. The present invention advantageously addresses these and other needs.

[0007] U.S. Pat. No. 5,660,163 discloses an implantable glucose sensor that is fabricated on a ceramic substrate. Working electrodes and other elements associated with the sensor are exposed to a conductive fluid contained within a reservoir or inner sheath that covers the substrate. An outer sheath is also placed over the sensor, with a window formed over one of the working electrodes. A

selected enzyme, such as glucose oxidate, is placed within the window. As disclosed in U.S. Pat. No. 5,660,163, five wires or conductors are attached to the electrodes and connected to electronic circuitry, e.g., a circuit such as is shown in FIG. 3 of the '163. U.S. Pat. No. 5,660,163 is incorporated herein by reference.

**[0008]** Additional features, aspects, and improvements of a glucose sensor of the type disclosed in U.S. Pat. No. 5,660,163 are further disclosed in U.S. Pat. No. 6,081,736; U.S. Pat. No. 6,119,028; and U.S. Pat. No. 5,999,848; each of which above-referenced patent applications is incorporated herein by reference.

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## Summary of the Invention

[0009] The implantable biocompatible device of the instant invention is coated with a thin film of ultra-nanocrystalline diamond. The device is generally an integrated circuit chip that contains electronic circuitry for communicating with living tissue. The biocompatible device may be either an implanted stimulator or a sensor of living tissue function. An ultra-nanocrystalline diamond thin film coating assures that the device will be biocompatible and hermetically sealed. Ultra-nanocrystalline diamond may be pattered by conventional methods, including photolithography, seeding, and oxygen etching, to expose electrodes to the living tissue. Further, the ultra-nanocrystalline diamond may be doped, by a variety of known methods, to create an electrically conductive area that acts as an electrode, which may in turn contact living tissue to be a stimulator or a sensor. The ultra-nanocrystalline diamond coating provides a conformal coating on the biocompatible device, which is of approximately uniform thickness around sharp corners and on high aspect-ratio parts. The conformal nature of the coating helps assure hermeticity and strength despite the presence of difficult to coat shapes.

## OBJECTS OF THE INVENTION

[0010] It is an object of the invention to provide an ultra-nanocrystalline diamond coated device that is hermetically sealed and biocompatible for implantation in a living body.

[0011] It is an object of the invention to provide an ultra-nanocrystalline diamond coated device that is has a uniform thickness coating around corners such that the coating maintains its hermetic sealing capability.

[0012] It is an object of the invention to provide an electrically insulating ultra-nanocrystalline diamond coated integrated circuit wherein the coating is patternable via conventional techniques to reveal electrodes.

[0013] It is an object of the invention to provide an ultra-nanocrystalline diamond coated integrated circuit wherein the coating contains openings to reveal electrodes.

[0014] It is an object of the invention to provide an electrically insulating ultra-nanocrystalline diamond coated integrated circuit wherein the coating is patterned by selective doping to yield integral electrodes.

[0015] It is an object of the invention to provide an implantable device, including electrodes and electronic circuitry that does not require a lid or cover for hermetically sealing hybrid electronic circuitry.

[0016] Other objects, advantages and novel features of the present invention will become apparent from the following detailed description of the invention when considered in conjunction with the accompanying drawing.

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## Brief Description of the Drawings

[0017] FIG. 1 illustrates a cross-sectional view of the integrated circuit coated with ultra-nanocrystalline diamond.

[0018] FIG. 2 depicts a cross-sectional view of an integrated circuit having a conductive portion of the ultra-nanocrystalline diamond coating.

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## Detailed Description of the Preferred Embodiments

[0019] Ultra-nanocrystalline diamond (UNCD) thin film coatings exhibit excellent mechanical, electrical, and electrochemical properties. Using a thin film coating deposition process, such as that disclosed by Gruen and Krauss (U.S. Pat. No. 5,772,760), yields a coating that is inherently low in porosity, electrically non-conductive and biocompatible. Coatings as thin as 40 nm have demonstrated excellent hermetic properties. UNCD thin film coatings are conformal when applied to complex or high aspect-ratio shapes. Since UNCD can be either patterned or selectively deposited, it also permits exposure of conductors and/or vias for interconnection with other components.

[0020] Characteristics of this UNCD coating that make it particularly well suited to the present invention are:

[0021] uniform morphology resulting in a very high bulk density,

[0022] highly conformal and able to cover very high-aspect ratio features uniformly,

[0023] electrical properties can be controlled by varying the deposition parameters, so as to make selected areas electrically conductivity,

[0024] low-temperature deposition thereby avoiding damage to electrical and passive components, and

[0025] easily patternable via selective seeding, photolithography, or oxygen etching.

[0026] UNCD coating properties are not all present in any other single coating candidate for microchip packaging. Alternative coatings are conventional chemical vapor deposited diamond thin films, diamond-like carbon, or SiC. UNCD coatings exhibit:

[0027] (a) extremely low surface roughness (20-30 nm), approximately independent of film thickness up to approximately 10 μm thickness;

[0028] (b) extremely good conformality when deposited on high aspect-ratio features;

[0029] (c) extremely low coefficient of friction;

[0030] (d) high hardness, fracture toughness, flexural strength, and wear life,

[0031] (e) low electrical conductivity, but can be doped to become conductive, and

[0032] (f) excellent resistant to degradation in living tissue environments.

[0033] The UNCD coating consists primarily of phase pure randomly oriented diamond crystallites. UNCD coatings are grown using a microwave plasma chemical vapor deposition technique involving a $C_{60}$/Ar or $CH_4$/Ar chemistry, which provides $C_2$ dimers as the main growth species that insert directly into the growing diamond lattice with a low energy barrier. The limited amount of atomic hydrogen in the plasma leads to a very high re-nucleation rate ($\sim 10^{11}$ $cm^{-2}$ $sec^{-1}$). This results in UNCD coatings with 2 to 5 nm grain size and 0.4 nm grain boundaries that provide the unique properties described herein. In addition, the low activation energy for $C_2$ species incorporation into the growing film yields UNCD films at temperatures as low as approximately 350° C. This temperature is very low compared to that required by many conventional coating processes, such as glass encapsulation or chemical vapor deposition.

[0034] The present invention uses the "chip" of an integrated circuit chip (which contains desired electronic circuitry) as the substrate for the stimulator or sensor, with the substrate and electronic circuitry being covered, as required, with a protective UNCD coating. Such approach advantageously eliminates the need for a hermetically sealed lid or cover, and thus allows the stimulator or sensor to be made much thinner than has heretofore been possible.

[0035] Integrated circuits that are implanted in a living body benefit from a UNCD coating that, in addition to biocompatibility, corrosion resistance, and hermeticity, can be patterned to expose the electrodes.

[0036] A UNCD protective coating covers the substrate, hermetically sealing the circuitry under the coating. Electrodes associated with the implantable device may be selectively left uncovered by the protective coating, thereby allowing such electrodes to be exposed to body tissue and fluids when the stimulator is implanted in living tissue. The exposed electrodes must be biocompatible. To this

end, the electrodes may be plated with a biocompatible metal, such as platinum or iridium or alloys of platinum and/or iridium.

[0037] Alternately, using any of several patterning techniques that are well known in the art, it is possible to expose selected electrical contacts by selectively removing portions of the UNCD coating. There are several known permutations and combinations of process steps that can lead to this result.

[0038] Also, the UNCD coating itself may be selectively doped so as to create electrically conductive integral portions of the coating that then act as electrodes, which in turn contact the living tissue.

[0039] The inert nature of a very thin coating of UNCD was demonstrated by the present inventors. A silicon substrate coated with 40 nm of UNCD film was exposed to silicon etchant having a composition of 67% $HNO_3$ and 33% HF, by volume. The etchant was placed drop-wise on the UNCD film, where it was allowed to stand at 60° C for one-hour. The coating had been unaffected when observed microscopically at 1000x after this exposure.

[0040] Therefore, the UNCD film coating may be used as part of a hermetic chip level packaging process to isolate implantable electronic and passive components from chemical or electrolytic attack in the body.

[0041] The UNCD coating on an integrated circuit is "conformal", which means that the coating has a uniform thickness as the coating follows the contours of the device. Achieving a conformal coating on high aspect-ratio parts and around sharp corners on these devices is a particular challenge for thin films that are deposited by other means.

[0042] In accordance with another aspect of the invention, an efficient integral capacitor may be formed between the stimulator and the living tissue by virtue of depositing a very thin layer of UNCD insulating film on the surface of the stimulator such that the thin film causes a capacitor to be formed. Such a capacitor can advantageously be used to effectively stop current flow to the living tissue, thereby avoiding harm to the tissue that is caused by electrical current flow, while allowing the stimulating voltage signal to pass to the tissue.

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[0043] The invention may further be characterized as a method of making an implantable device that is either a stimulator or a sensor, where the device includes a substrate, electrodes formed on the substrate, and electrical circuitry formed on the substrate. Such method includes the steps of: (a) forming the electrical circuitry on the surface of a semiconductor substrate; (b) forming electrodes on the semiconductor substrate; (c) electrically interconnecting the electrodes with the electrical circuitry through the use of conductive paths that pass through or on the body of the semiconductor substrate; and (d) depositing a protective coating of UNCD over the entire surface area of the substrate, except for select areas of the electrodes, so that all but the exposed area of the electrodes is sealed and protected.

[0044] FIG. 1 provides a cross-sectional view of a preferred embodiment of a coated integrated circuit 1. Due to the extremely thin film that is required, these figures are not drawn to scale. The integrated circuit is shown, where the silicon substrate 3 contains an electrode 5 on one surface that is connected by metal trace 7 to active circuitry 9. The silicon substrate 3 is coated with an ultra-nanocrystalline diamond 11. The ultra-nanocrystalline diamond 11 coating has been removed in a selected portion to expose electrode 5 such that electrode 5 can contact living tissue directly when implanted. The ultra-nanocrystalline diamond 11 has an approximately uniform thickness and has rounded corners 13 which are formed as part of the normal application process. The rounded corners 13 are an advantage for implanted ultra-nanocrystalline diamond coated devices such as coated integrated circuit 1 because they eliminate sharp corners and sharp edges that might otherwise create stress concentrations in the living tissue which could damage the tissue.

[0045] FIG. 2 provides a cross-sectional view of an integrated circuit as in FIG. 1, however, the normally electrically insulating ultra-nanocrystalline diamond 11 has been doped in a selected area to provide electrically conductive doped ultra-nanocrystalline diamond electrode 15. This preferred configuration allows the ultra-nanocrystalline diamond 11 to be completely hermetically sealed around the

silicon substrate 3, thereby protecting the silicon substrate 3 and electrodes 5 from exposure to living tissue.

[0046] Obviously, many modifications and variations of the present invention are possible in light of the above teachings. It is therefore to be understood that, within the scope of the appended claims, the invention may be practiced otherwise than as specifically described.

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